IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		§		
		§		
	Gad KEREN et al	§		
		§	Confirmation No.:	2139
Serial No.:	09/839,643	§		
		§		
Filed:	April 20, 2001	§	Group Art Unit:	3772
		§		
For:	METHODS AND APPARATUS FOR REDUCING LOCALIZED CIRCULATORY SYSTEM PRESSURE	§		
		§		
		§	Attorney Docket:	**34948**
		§		
Examiner:	Camtu Tran NGUYEN	§		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Following please find a five page paper setting forth the reasons why the Examiner's Rejection dated September 1, 2010, should not be maintained.

Applicants respectfully request that the Panel issue a Notice of Allowance in this case.

Respectfully submitted,

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ARGUMENTS

In the Office Action dated September 1, 2010, claims 40, 50, 59, 68-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108 were rejected.

The Examiner rejected claim 40, 50, 59, 69-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108 under 35 U.S.C. §102(e) as being unpatentable over Wolf et al. (US 2002/0165606).

The Examiner rejected claim 68 under 35 U.S.C. §103(a) as being unpatentable over Wolf et al. in view of Wilk (US 7,294,115).

Claims 48, 59, 84 and 103 are the only independent claims in the Application.

Applicant would like to point out that the Examiners regrettable withdrawal of the subject matter allowed in the previous office action is disappointing and dismaying, especially in light of the fact that the references used as a basis for the instant rejections were previously considered by the Examiner.

Wolf et al. was considered by the Examiner as US 2002/0165606 in the office action issued on April 27, 2010 and as US 6,641,610 (the patent issued from US 2002/0165606) in the office action issued on November 12, 2009. Furthermore, Wilk (US 7,294,115) which is assigned to PeriCardia, the same assignee of the Wolf et al reference was also considered by the Examiner in previous office actions. The Wilk reference teaches subject matter which is substantially identical in concept to that of Wolf et al.

In his rejection, the Examiner refers to paragraph [0028] as evidence to positioning of the valved-shunt of Wolf et al. (shown in Figures 2, 4 and 7) between two heart chambers. Paragraph [0028] of Wolf et al. recites the following (emphasis added):

"As used herein, the term "heart chamber" primarily refers to the interior, or lumenal, aspect of the left or right ventricle or the left or right atrium. The term "conduit," "stent," and "tube" herein refer to physical structures, preferably primarily artificial, that can be positioned between two or more chambers or vessels, to allow blood flow from one chamber or vessel to another. A "shunt" is any natural or artificial passage between natural channels, such as heart chambers or blood vessels. The conduit in the preferred arrangement can be made of a variety of materials, including various metals, such as nitinol, or plastics."

In referring to chambers and vessels, Wolf et al. generally describe where conduits can be positioned and does not specifically teach inter-atrial conduits. The preceding paragraph [0027] which describes the problem to be solved provides context to paragraph [0028]:

"As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the remainder of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients."

The Examiner further points out that that Wolf et al. disclose that high pressure blood flow causes the valve in the shunt to open allowing blood flow from the left atrium to the right atrium. Thus, the Examiner concludes that the shunt of Wolf et al. would perform the method of decreasing blood pressure in a heart chamber. The Examiner does not point out however, where in Wolf et al. such a method is taught or suggested.

Wolf et al. do not teach the present method nor is such a method or the pathology associated therewith mentioned or suggested by Wolf et al. The present inventors were the first to recognize the importance of adjustable flow regulation between atria and the need for an adjustable flow regulating mechanism that provides such functionality in treatment of pulmonary edema secondary to CHF.

The present flow regulating mechanism addresses several clinical conditions which <u>are not mentioned or considered by Wolf et al.</u> and is specifically designed for intra-septal positioning and for providing <u>controlled flow</u> between the left and right atria in order to treat pulmonary edema while also:

(i) Ensuring that the cardiac output is not reduced in the CHF patients - the CHF patient already suffers from reduced cardiac output. If the shunt is fully open in the chronic phase (mean Left-Right atriums pressure gradients <12 mmHg) there will be

constant flow between the left and right atria and long term reduction in cardiac output which is unacceptable in CHF patients. In the acute phases of CHF it is acceptable to have a slight reduction in the cardiac output since the patient will develop life threatening pulmonary edema if the pressures are not reduced immediately.

(ii) Eliminating risk of right to left shunting of blood and avoid thrombus passing from the venous system to the systemic system.

(iii) Providing a range of operation between minimal and maximal shunting. Such a range of operation is necessary in order to accommodate for inter-subject variation in pressure gradients and slight modifications to the sensitivity of the flow regulating mechanism caused by tissue ingrowth over time.

A device provided with an adjustable flow regulating mechanism with pathology-specific functionality (in as far as flow regulation and positioning) and a method of using same were not described or suggested by Wolf et al. or in fact known in the art prior to filing of the instant application.

In fact, Wolf et al. only disclose devices and methods which are suitable for forming bypasses and not for treating conditions such as pulmonary edema secondary to CHF, as is specifically recited in paragraph [0056] of Wolf et al.:

"The present vascular conduit and valve system provides significant improvements in the present treatment of blockages and significant stenoses in the coronary artery."

Although Wolf et al. refer to an atrium, such references relate to chambers which can be used in a coronary bypass as is clearly evident from claims 1, 4 and 5 of this application which state:

1. A coronary bypass conduit comprising: a hollow tube having an interior and an exterior and adapted to be positioned in a wall of a heart between a coronary artery and a heart chamber; and an artificial one-way valve positioned within the interior of said tube.

4. The conduit of claim 1, wherein said heart chamber is a left atrium.

5. The conduit of claim 1, wherein said heart chamber is a right atrium.

Thus, Wolf does not teach or suggest regulating pressure between two heart chambers or specifically between two atria or a conduit designed for such purposes.

Wolf mentions a heart septum in the context of tissue which can be traversed in order to achieve the flow path desired (e.g. from a ventricle to an artery). Paragraphs 0029 and 0031 of Wolf et al. recite the following (emphasis added):

"[0029] As used herein, the term "heart wall" comprises any one or more of the following portions or layers of the mammalian heart: the epicardium, myocardium, endocardium, pericardium, interatrial septum, and interventricular septum.

[0031] In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other nonmyocardial and even noncardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc."

It is clear that in reciting "septum" Wolf et al. refer to tissue through which a conduit can be routed and not intraseptal implantation for the purpose of regulating pressure between atria. Since Wolf et al. do not teach regulation of atrial pressure, no other interpretation for this use of a "septum" or for the description of paragraph [0028] can be made.

Thus, it is submitted that the Examiner has not provided a *prima facie* case in support of the rejections of the claims since the above-mentioned references fail to teach:

1. "implanting a valve in a heart septum between two heart atria" (independent claim 49) or suggest treatment of the pathology addressed by the present invention;

2. that the valve of the shunt is "configured for opening when a pressure differential between said left atrium and said right atrium is 12 mmHg or above" (independent claim 59);

3. "implanting a valve in a heart septum between two heart atria" and that the "valve opens responsive to a pressure level of an exacerbated state of heart failure but not under normal pressures of systole and diastole of a normal heart" (independent claim 84); and

4. a shunt having a "controller adapted to control flow through said shunt in response to readings from the sensor indicating a pressure above 12mmHg" as (independent claim 103).

Thus, Applicant believe that the Rejection dated September 1, 2010 is not proper and without basis, specifically that the rejections arise from the Examiner not appreciating the essence of the cited art and ignoring the arguments brought up by the Applicants. Applicants believe that independent claims 48, 59, 84 and 103 are neither anticipated by nor rendered obvious over the cited art.

Since these independent claims are patentable over the cited art, claims which are respectively dependent therefrom, are in condition for allowance.